Paper No. 20

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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Ex parte ADEL KAFRAWY and FIDELIS C. ONWUMERE

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Appeal No. 2004-0479
Application No. 09/780,864

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ON BRIEF

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Before ABRAMS, HAIRSTON, and FLEMING, ***Administrative Patent Judges.***

FLEMING, ***Administrative Patent Judge***.

DECISION ON APPEAL

This is a decision on appeal from the final rejection of claims 18-25. Claims 1-17 have been canceled.

INVENTION

Appellants' invention relates to an intravenous catheter assembly (56), which includes a hollow hub (42), a catheter (50), and a needle (82). See specification, page 6, lines 10-16; page 12, line 14 to page 13, line 6; and Figs. 3-5. The catheter (50) has a length of at least 12 mm (see TABLE on page 13 of

specification), a first end (62) secured to the hub (42) in a unitary construction, a second end (64) distant from the hub (42), and a passage (60, 66) extending from the hub (42) out of the second end (64). See Fig. 3. The needle (82) is removably located within the passage (60, 66) and has a sharp tip (86) in proximity to the second end of the catheter (50). See specification, page 13, lines 6-8. The hub (42) and the catheter (50) are preferably made of the same material. See specification, page 15, lines 8-10. Suitable materials include a polyamide, a blend of acrylonitrile/butadiene/styrene and polyurethane, polyetheramide, a fluorinated ethylene propylene copolymer polypropylene, an ethylene propylene copolymer, polypropylene, polyurethane, and a blend of a polyamide and a polyetheramide. See specification, page 15, line 11 to page 17, line 17. The hub (42) has a luer lock formation (58) on a side thereof. See specification, page 12, lines 8 and 9.

Claim 18 is representative of the claimed invention and is reproduced as follows:

18. An intravenous catheter assembly which includes:

a hollow hub;

a catheter having a length of at least 12 mm, having a first end and a second end, the second end distant from the hub, and a passage extending from the hub out of the second end; and

a needle, removably located within the passage, having a sharp tip in proximity to the second end of the catheter,

wherein the hub and catheter are formed as a single piece.

REFERENCES

The references relied on by Examiner are as follows:

Cambron et al. (Cambron)	4,722,344	Feb. 2, 1988
Kitou et al. (Kitou)	5,993,436	Nov. 30, 1999

REJECTIONS AT ISSUE

Claims 18-25 stand rejected 35 U.S.C. § 103 as being obvious over Cambron in view of Kitou.

Throughout our opinion, we make references to the brief, and answer[1] for the respective details thereof.

OPINION

[1]Appellants filed an appeal brief on June 26, 2003. We will refer to this brief as the brief. The Examiner mailed an Examiner's answer on September 30, 2003. We will refer to the Examiner's answer as the answer. Appellants filed a reply brief on November 7, 2003. The Examiner has noted and entered the reply brief on November 25, 2003. We will refer to Appellants' reply brief as the reply brief.

With full consideration being given to the subject matter on appeal, Examiner's rejections and the arguments of Appellants and Examiner, for the reasons stated ***infra***, we affirm the Examiner's rejection of claims 18-25 under 35 U.S.C. § 103.

I. *Whether the Rejection of Claims 18 and 21-25 Under 35 U.S.C. § 103 as Being Obvious over Cambron in View of Kitou is Proper?*

We note that Appellants group claims 18 and 21-25 as group 1. See page 4 of the brief. Furthermore, Appellants argue claims 18 and 21-25 as a single group. See pages 5-8 of the brief and pages 2-10 of the reply brief. 37 CFR § 1.192 (c)(7) (July 1, 2002) as amended at 62 Fed. Reg. 53169 (October 10, 1997), which was controlling at the time of Appellants' filing of the brief, states:

> For each ground of rejection which Appellant contests and which applies to a group of two or more claims, the Board shall select a single claim from the group and shall decide the appeal as to the ground of rejection on the basis of that claim alone unless a statement is included that the claims of the group do not stand or fall together and, in the argument under paragraph (c)(8) of this section, Appellant

> explains why the claims of the group are believed to be separately patentable. Merely pointing out differences in what the claims cover is not an argument as to why the claims are separately patentable.

We will, thereby, consider Appellants' claims 18 and 21-25 as standing or falling together and we will treat claim 18 as a representative claim of that group. "If the brief fails to meet either requirement, the Board is free to select a single claim from each group of claims subject to a common ground of rejection as representative of all claims in that group and to decide the appeal of that rejection based solely on the selected representative claim." ***In re McDaniel***, 293 F.3d 1379, 1383, 63 USPQ2d 1462, 1465 (Fed. Cir. 2002). See also ***In re Watts***, 354 F.3d 1362, 1369, 69 USPQ2d 1453, 1457 (Fed. Cir. 2004).

In rejecting claims under 35 U.S.C. § 103, the Examiner bears the initial burden of establishing a ***prima facie*** case of obviousness. ***In re Oetiker***, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). See also ***In are Piasecki***, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984). The Examiner can satisfy this burden by showing that some

objective teaching in the prior art or knowledge generally available to one of ordinary skill in the art suggests the claimed subject matter. ***In re Fine***, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). Only if this initial burden is met, does the burden of coming forward with evidence or argument shift to Appellants. ***Oetiker***, 977 F.2d at 1445, 24 USPQ2d at 1444. See also ***Piasecki***, 745 F.2d at 1472, 223 USPQ at 788. An obviousness analysis commences with a review and consideration of all pertinent evidence and arguments. "In reviewing the [E]xaminer's decision on appeal, the Board must necessarily weigh all of the evidence and argument." ***In re Oetiker***, 977 F.2d at 1445, 24 USPQ2d at 1444. "[T]he Board must not only assure that the requisite findings are made, based on evidence of record, but must also explain the reasoning by which the findings are deemed to support the agency's conclusion." ***In re Lee***, 277 F.3d 1338, 1344, 61 USPQ2d 1430, 1434 (Fed. Cir. 2002).

With respect to Cambron, Appellants argue that because Cambron's description of Fig. 2 in column 4, lines 6-9 states that the catheter is attached to the hub, Cambron does not

teach "the hub and catheter are formed as a single piece" as recited in Appellants' claim 18. Appellants further argue that the Examiner's interpretation of a drawing does not prevail over the language of the specification.

Our reviewing court states in ***In re Zletz***, 983 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) that "claims must be interpreted as broadly as their terms reasonably allow." Our reviewing court further states "[t]he terms used in the claims bear a 'heavy presumption' that they mean what they say and have the ordinary meaning that would be attributed to those words by persons skilled in the relevant art." ***Texas Digital Systems Inc. v. Telegenix Inc.***, 308 F.3d 1193, 1202, 64 USPQ2d 1812, 1817 (Fed. Cir. 2002).

Upon our review of Appellants' specification, we fail to find any definition of the term "single piece" that is different from the ordinary meaning. Furthermore, we note that the issue before us is what is ordinary meaning of the term "single" since it is not disputed that the hub or catheter can be considered as a piece of the apparatus. The question is whether the hub and catheter is a single piece.

We find the ordinary meaning of the term "single" is best found in the dictionary. We note that the definition most suitable for "single" is "consisting of one form or part."[2]

Now, the question before us is what would Cambron have taught to one having ordinary skill in the art? To answer this question, we find the following facts:

1. Cambron's Figure 2 shows an uninterrupted solid outside perimeter line connecting catheter 15 and hub 16.

2. Cambron's Figure 2 shows within the passageway an uninterrupted solid inside perimeter line connecting catheter 15 and hub 16.

3. Cambron's Figure 2 does not show a horizontal line connecting the outside perimeter line and the inside perimeter line at the interface between catheter 15 and hub 16, but instead shows a solid material.

4. Cambron's Figure 2 shows that the catheter 15 and hub 16 have the same cross-hatching.

[2] The American Heritage Dictionary, Second College Edition, 1982, page 1143. Copy provided to Appellants.

5. Cambron's Figure 2 shows an uninterrupted solid outside perimeter line connecting hub 13 and blood-detecting chamber 14.

6. Cambron's Figure 2 shows within the passage way an uninterrupted solid inside perimeter line connecting hub 13 and blood-detecting chamber 14.

7. Cambron's Figure 2 does not show a horizontal line connecting the outside perimeter line and the inside perimeter line at the interface between hub 13 and blood-detecting chamber 14, but instead shows a solid material.

8. Cambron's Figure 2 shows that the hub 13 and blood-detecting chamber 14 have the same cross-hatching.

9. Cambron's Figure 2 shows an uninterrupted solid outside perimeter line connecting plug 20 and diaphragm 23.

10. Cambron's Figure 2 shows an uninterrupted solid inside perimeter line connecting plug 20 and diaphragm 23.

11. Cambron's Figure 2 does not show a horizontal line connecting the outside perimeter line and the inside perimeter line at the interface between plug 20 and diaphragm 23, but instead shows a solid material.

12. Cambron's Figure 2 shows that the plug 20 and diaphragm 23 have the same cross-hatching.

13. Cambron states in the specification that the "entire hub and blood-detecting chamber assembly can be molded in one piece from a suitable clear plastic material." See Cambron, column 4, lines 2-4.

14. Cambron states in the specification that "[p]lug 20 can be molded in one piece with diaphragm 23." See Cambron, column 4, lines 14 and 15.

15. Cambron states in the specification that "[c]atheter 15 is attached to a hub 16 at its proximal end." See Cambron, column 4, lines 6-9.

16. Cambron states in the specification that "[c]atheter 15 is formed from a polyurethane." See Cambron, column 4, line 48.

17. Cambron states in the specification that "[p]olyurethane produced according to this invention can be thermoplastic or thermoset polymers. Thermoplastic polyurethanes are often preferred because they can be melt-processed by conventional polymer techniques, such as injection molding, extrusion, etc." See Cambron, column 6, lines 29-33.

18. Cambron provides no other teachings other than injection molding or extrusion for making the catheter.

"Absent any written description in the specification of quantitative values, arguments based on measurement of a drawing are of little value." ***In re Wright***, 569 F.2d 1124, 1127, 193 USPQ 332, 335 (CCPA 1977). Also, we note that "Patent drawings are not working drawings." ***See In re Wilson***, 312 F.2d 449, 454, 136 USPQ 188, 192 (CCPA 1963). However, this does not mean that the drawing cannot provide any teachings to those skilled in the art. "We did not mean that things patent drawings show clearly are to be *disregarded*." ***In re Mraz***, 455 F.2d 1069, 1072, 173 USPQ 25, 27 (CCPA 1972).

Now, we must determine what does the Cambron's Figure 2 show. Cambron's Figure 2 shows three main components which fit into each other to make up the catheter assembly 10. The three main components are the catheter and hub assembly (without an element number), the blood-detecting chamber assembly (without an element number) and the plug (element 20). The catheter and hub assembly includes the catheter 15 and hub 16. The blood-detecting chamber assembly includes the

blood-detecting chamber 14 and hub 13. The plug 20 includes the neck 22 and diaphragm 23. As found above, all three main components are shown in the drawing as three single pieces. Also, as found above, the specification states that the blood-detecting chamber and the plug are molded in one piece. For the catheter and hub assembly, the specification is silent as to how the catheter and hub assembly is molded. However, when considering that the drawings show each of the three components as one piece and that the specification states for two of the components that they are molded as one piece, one of ordinary skill in the art would have also concluded that the catheter and hub assembly is to be molded as one piece as well.

Appellants argue because the specification states that the catheter 15 is attached to hub 16, they must be two separate pieces. However, we do not find that this alone would lead those skilled in the art to conclude that the catheter and hub assembly is made up of two pieces. We note that Cambron's specification does not provide a definition of "attached." The dictionary definition for "attached" is connected or

joined to.[3] We note that the drawing shows the catheter 15 joined to the hub 16. Thus, the specification is not inconsistent with what is shown in the drawing as the catheter and hub joined as a single piece.

We further note that the teaching found in Cambron, column 4, lines 6-9, which states that "[c]atheter 15 is attached to a hub 16 at its proximal end" is not a teaching as to how the piece is formed, but only a description of catheter and hub assembly. As found above, Cambron only teaches that the assembly is formed by injection molding or extrusion as a single piece. Cambron does not provide a teaching of an alternative method of making the catheter and hub as separate pieces and then use some other method to put the two pieces together. This is further buttressed by the factual finding that Cambron teaches that the hub and catheter is to be made of polyurethane. Since the only method of making the assembly suggested by Cambron is injection molding or extrusion, those skilled in the art would be led to make the

[3] The American Heritage Dictionary, second college edition, 1982, page 139. Copy provided to Appellants.

assembly in one step wherein the catheter and hub are made as a single piece as shown in the drawing.

Finally, even if we were persuaded by Appellants' arguments that Cambron's hub and catheter are made as separate pieces and then attached together to become a single assembly, we would still fail to find that Appellants' claim language would distinguish over this teaching. We note that the language "the hub and catheter are formed as a single piece" does not preclude how the catheter and hub are made. The claim language is only directed to the final resulting assembly of the catheter and hub. Therefore, even if the prior art teaches a separate catheter and a separate hub which then are made into becoming a single form or part by some means of attachment, the prior art would then read on "the hub and catheter formed as a single piece" as recited in Appellants' claim 18.

In summary, because the drawings show the catheter 15 and hub 16 as a single, homogeneous piece, and this is consistent with Cambron's specification as a whole, we find that Cambron

teaches "the hub and catheter are formed as a single piece" as recited in Appellants' claim 18.

Appellants argue that the Examiner improperly combined Cambron and Kitou. In particular, Appellants argue that the combination of Cambron with Kitou is improper since the Examiner fails to establish a motivation for combining the references including establishing that the references suggest the desirability of the claimed invention. See page 7 of the brief.

We note that the Examiner states that Cambron teaches all of the limitations of Appellants' claim 18 except for the limitation "a catheter having a length of at least 12 mm." See page 5 of the answer.

We find that Cambron teaches catheters that are used for arterial, intravenous and central line vascular catheters. See Cambron, column 7, lines 26-32. We further find that Cambron is silent as to the length of these catheters. We find that Kitou teaches catheters that are used for an indwelling catheter to be left in place in a blood vessel to perform infusion, introduction of a medicinal solution, blood

transfusion, blood collection, monitor of blood circulation, *etc*. See Kitou, column 1, lines 5-9. Thus, Kitou teaches catheters for the same purpose as the Cambron catheter. We find that Kitou teaches that the useful length for catheters used for these purposes are to be 25 mm. See Kitou, column 5, lines 25 and 48 and column 6, lines 7, 25, 45 and 63. Therefore, because those skilled in the art would have to determine the length of Cambron's catheters for use in Cambron's taught medical applications, they would have looked to Kitou's teachings that 25 mm length for the length of the catheter to be used in the same medical applications. Therefore, we will sustain the Examiner's rejection of claims 18 and 21-25 under 35 U.S.C. § 103.

II. *Whether the Rejection of Claim 19 Under 35 U.S.C. § 103 as Being Obvious over Cambron in View of Kitou is Proper?*

Appellants argue that neither Cambron nor Kitou teaches a catheter and hub formed of the same material. See page 8 of the brief and pages 10-12 of the reply brief.

We note that claim 19 recites "wherein the hub and the

catheter are made of the same material." Furthermore, upon our review of Cambron, we find the following facts:

1. Cambron states in the specification that "[i]n addition, it would be advantageous if catheters were optical transparent so that the flow of fluids therethrough could be observed." See Cambron, column 1, lines 14-16.

2. Cambron states in the specification that "[b]lood flowing into chamber 14 can then be detected by the operator through the transparent wall of the chamber." See Cambron, column 4, lines 37-39.

3. Cambron states in the specification that "[t]he term 'optical transparency' is used herein to mean a material which, when formed into a catheter or other shaped article, will allow the presence of blood or other fluids to be visible from outside the catheter under normal lighting conditions. For example, a polyurethane is optically transparent if such a material, when formed into a tube having a wall thickness of about 0.01 inches or less, allows the passage of blood therein to be observed by the naked eye from outside the tube under

normal lighting conditions." See Cambron, column 6, lines 17-28.

4. Cambron states in the specification that "[i]t is generally desirable that catheters be radiopaque because it is often necessary to determine the precise location of a catheter within its host by X-ray examination." See Cambron, column 1, lines 11-14.

5. Cambron states in the specification that "[i]n U.S. Patent Nos. 3,749,134 and 3,901,829, Slingluff describes yet further attempts to produce catheters which are optical transparent and radiopaque. In these patents, Slingluff suggests blending a small amount of a diol of tetrabromophthalic anhydrite and a plasticizer with the thermoplastic resin employed in forming the catheter." See Cambron, column 2, lines 26-32.

6. Cambron states in the specification that "[u]nfortunately, it has been discovered that such physical blends suffer from certain drawbacks. For example, the material blended in to add radiopaque often can be leached from the material. In extreme cases, the material can be leached from the catheter and absorbed systematically by the host." See Cambron, column 2, lines 56-61.

7. Cambron states in the specification that "[t]his invention relates to polyurethanes, and to catheters and other articles formed from the polyurethanes, which are radiopaque due to the incorporation of halogenated moieties into the polymer structure. In preferred embodiments, the polyurethanes are additionally optical transparent." See Cambron, column 3, lines 11-16.

8. Cambron states in the specification that "[i]mportantly, the polyurethanes of this invention are radiopaque because of structural units contained within the polymer itself. This eliminates the necessity to blend a material with the polymer to provide radiopaque. Thus, the disadvantage of physical blends are avoided." See Cambron, column 3, lines 30-34.

9. Cambron states in the specification that "[P]olyurethanes which are radiopaque and yet optically transparent provide a unique combination of desirable properties for catheters in a polymer noted for its biocompatibility and other advantageous properties for medical applications." See Cambron, column 3, lines 42-46.

10. Cambron states in the specification that "[c]atheter 15 is formed from a polyurethane which is radiopaque, and preferably optical transparent." See Cambron, column 4, lines 48-49.

As pointed out above, Cambron's figure 2 shows the catheter 15 and hub 16 assembly being one piece and have the same cross hatching denoting that the assembly is made of one material. Although the specification only specifically states that the catheter 15 is made of polyurethane, when reading Cambron's specification as a whole, those skill in the art would have concluded that catheter 15 and hub 16 are to be made of polyurethane as shown in figure 2.

From the above facts, Cambron teaches that the catheter and hub assembly is be made of polyurethane due to polyurethane's optical transparent characteristic. Cambron teaches that polyurethane's optically transparent characteristic is important because it allows the operator to detect or observe the flow of blood from the vein of the host to the blood chamber 14 by the naked eye under normal lighting condition. Catheter 15 and hub 16 are in this pathway and thereby Cambron would have taught those skilled in the art

that it is important to have the catheter 15 and hub 16 transparent and made of polyurethane.

Cambron also teaches that the catheter and hub assembly is to be made of polyurethane due to polyurethane's radiopaque properties. Cambron teaches that polyurethane's radiopaque properties are important because it is often necessary to determine the precise location of a catheter within its host by X-ray examination. Therefore, one of ordinary skill would have recognized that catheter 15 and hub 16 are to be made of polyurethane for this reason as well.

Furthermore, we find that Cambron teaches the use of polyurethane in order to avoid the leaching of the blended material, which adds radiopaque, into the patient's body. We find that since Cambron teaches to form the catheter of polyurethane, Cambron also teaches or suggests to form the hub of polyurethane so that the blended material in the hub would not leach into the patient's body when the hub is in contact with fluids that are or could be injected into the patient's body. This finding is in line with Cambron's explicit teachings that Cambron's invention relates to polyurethanes,

and to catheters *and other articles* formed from the polyurethane. Therefore, we will sustain the Examiner rejection of claim 19.

III. *Whether the Rejection of Claim 20 Under 35 U.S.C. § 103 as Being Obvious over Cambron in View of Kitou is Proper?*

Appellants argue that Cambron fails to teach "wherein the hub has a luer lock formation thereon" as recited in claim 20. See pages 9 and 10 of the brief. Appellants argue that because Cambron describes the hub 16 having a "female luer end," the hub is a luer slip connection and not a luer lock having a hub of a projection of sufficient size to engage a complementary threaded coupling device. Page 10 of the brief.

We find that Cambron's teaching "the open female luer end of hub 16" as described in col. 4, lines 45 and 46, reads on Appellants' claimed limitation "wherein the hub has a luer lock formation." Appellants' specification describes that "the hub 42 has a luer lock formation 58 on a side thereof opposing the catheter 50, and a first passage 60 therethrough" in lines 8 and 9 on page 12 of the specification. More importantly, Appellants' Figures 3-5 show that the luer lock

formation is a rim or lip 58 of the hub 42. Appellants do *not* show the hub 42 having a projection of sufficient size to engage a complementary threaded coupling device as now argued. Appellants' luer lock formation is shown to be identical or substantially identical to the rim or lip formed at the female luer end of Cambron's hub 16. Therefore, we find that Cambron's hub 16 reads on "the hub has a luer lock formation thereon" as recited in Appellants' claim 20. Therefore, we will sustain the rejection of claim 20.

In view of the foregoing discussion, we have sustained the rejection under 35 U.S.C. § 103 of claims 18-25.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR

§ 1.136(a).

AFFIRMED

NEAL E. ABRAMS Administrative Patent Judge	)	
KENNETH W. HAIRSTON Administrative Patent Judge	)	BOARD OF PATENT APPEALS AND INTERFERENCES
MICHAEL R. FLEMING Administrative Patent Judge	)	

MRF/lbg

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